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APPLICATION NO. 09/185,782	FILING DATE 11/04/98	FIRST NAMED INVENTOR BARRAWS	ATTORNEY DOCKET NO. 09125/001001
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EXAMINER RUSSEL, J

ART UNIT 1654	PAPER NUMBER 3
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DATE MAILED: 04/30/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/85,732

Applicant(s)

T. Barrows et al

Examiner

J. Russel

Group Art Unit

1654

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11-4-1998
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-162 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-162 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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1. The consent of assignee to the reissue and the offer to surrender have been received.

The request for transfer of original drawings has been received. This request will be treated as a request to transfer the formal drawings from the original patent file to the reissue application. See MPEP 1413.

Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,583,114, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP §§ 1404, 1442.01 and 1442.04.

2. The petition to correct the inventorship by adding Matthew T. Scholz has been received.

However, because the petition was also filed in the patented file and is currently being considered by Certificate of Corrections Branch, the examiner will await their decision on the petition.

Assuming that the petition is granted by Certificate of Corrections Branch, it will be necessary for Applicants to submit a copy of the Certificate of Correction with their next response.

3. The disclosure is objected to because of the following informalities: Because of an insufficient top margin, the page of the instant specification corresponding to column 3 of the patent has been partially deleted by hole punching. It will be necessary for Applicants to resubmit the entire page in their response to this Office action. Appropriate correction is required.

4. The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR

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1.175(a)(1) and MPEP § 1414. While there is some discussion of the concept of error in the reissue declaration filed November 4, 1998 (see especially page 1, last full sentence), this discussion essentially does no more than quote from the rules governing all reissue applications. Such summarization of the rules does not constitute a specific identification of at least one error in the patent. See MPEP 1414, especially page 1400-13, last paragraph, through page 1400-14, first column, first full paragraph.

Claims 1-162 rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175 and MPEP 1444.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

5. Claims 18-37, 40-71, 74-103, 106-138, and 141-162 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: Claims 18, 52, 84, and 119 now recite the use of compositions comprising an albumin protein not limited to a serum albumin. However, the original disclosure of albumin proteins is limited to serum albumin, and the new claim language embraces non-serum albumin such as lactalbumin, ovalbumin, and vegetable albumins.

Accordingly, the new claim language constitutes new matter. Claims 27, 61, 93, and 128 recite a peel strength of 0.08 lb/in or more; the range contains no upper limit to the peel strength.

However, the original disclosure is limited to peel strengths no higher than about 0.6 lb/in (see Figure 2). Disclosure of a limited range of peel strengths is not support for a broader range of

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peel strengths having no upper limit. Accordingly, the new claim language constitutes new matter. Claims 28-31, 62-65, 94-97, and 129-132 recite the burst pressure ranges of "greater than about 10 mmHg", "about 34 mmHg or greater", "about 90 mmHg or greater", and "about 130 mmHg or greater"; these ranges contain no upper limit to the burst pressure. However, the original disclosure is limited to burst pressures of no higher than 196 mmHg. Disclosure of a limited range of burst pressures is not support for a broader range of burst pressures having no upper limit. Further, the original disclosure is limited to burst pressures of no lower than 30 mmHg when serum albumin is used as the protein. Disclosure of burst pressures for non-albumin proteins is not support for burst pressures for albumin proteins because there is no expectation that the burst pressures would be the same regardless of the protein used. Accordingly, the new claim language constitutes new matter. There is no original disclosure of an oligomeric diradical represented by the last formula at claim 37, line 18; claim 71, line 18; claim 103, line 18, and claim 138, line 18. Compared to the original disclosure, it is believed that the formula in the new claims is missing a terminal C(O)- group. There is no original disclosure of a crosslinking agent concentration as low as 5 mg/ml as recited in claims 40, 74, 106, and 141. The original disclosure (see, e.g., patent claim 1, part (ii), and claim 5) recites a lower limit only as low as 5 mg/ml. It is believed that the lower limit in the new claims may be a misprint.

6. Claims 1-37, 40-71, 74-103, 106-138, and 141-162 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. To the extent that the claims contain new matter under 35 U.S.C. 251, they also lack written description in the original disclosure under 35 U.S.C. 112, first paragraph. See the above rejection under 35 U.S.C. 251 set forth in paragraph 5. In addition, the limitation "a burst strength greater than about 10 mmHg" in unamended patent claims 1 and 17 is deemed not to be supported by the original disclosure for the same reasons that the limitation contained in the new claims added in this reissue application is deemed to constitute new matter.

7. Claims 18-162 are rejected under 35 U.S.C. 251 as being an improper recapture of claimed subject matter deliberately canceled in the application for the patent upon which the present reissue is based. As stated in *Ball Corp. v. United States*, 221 USPQ 289, 295 (Fed. Cir. 1984):

The recapture rule bars the patentee from acquiring, through reissue, claims that are of the same or broader scope than those claims that were canceled from the original application.

Claims 18-162 are broader in scope than the patented method claims in terms of the protein, protein concentration, crosslinking agent concentration, and burst strength limitation. In particular, the patented method claims require the use of serum albumin, whereas the new claims added in this reissue application permit the use of any albumin. The patented method claims require a protein concentration of about 20-60 wt/vol %, whereas the new claims added in this reissue application permit the use of any concentration of protein. The patented method claims require a crosslinking agent concentration of about 50-800 mg/ml, whereas the new claims added in this reissue application permit the use of any concentration of crosslinking agent. The patented

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method claims require a burst strength of greater than about 10 mmHg, whereas the new claims added in this reissue application permit any burst strength. These limitations were inserted into the claims eventually allowed in the patent by the amendment filed June 12, 1995 in order to overcome a prior art rejection. In particular, the remarks accompanying the amendment filed June 12, 1995 (see, e.g., page 7, line 7, and page 8, lines 2-5) and the further remarks filed January 24, 1996 (see, e.g., page 2, line 20, and page 3, lines 2-5) in response to another prior art rejection refer to these limitations as helping to distinguish over the prior art on the basis of a patentable difference in terms of composition and characteristics of the composition. It is impermissible to claim subject matter in a reissue application which was intentionally canceled during prosecution of the patent application in order to obtain the patent. See also *In re Clement*, 45 USPQ2d 1161 (CAFC 1997).

8. Claim 1-7, 9-17, 37-42, 44-47, 51, 71-76, 78-81, 103-108, 110-113, 130-132, 138-143, 145-148, 153, and 157 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the definition of G in claims 1, 17, 37, 71, 103, and 138, "or" should be changed to "and" so that standard Markush terminology is used. There is no antecedent basis in the claims for the phrase "The adhesive mixture" at claim 2, line 1. Note that the independent claim is drawn to an adhesive composition, and that its two main components are aqueous mixtures. It is believed that "mixture" should be changed to "composition". Similarly, there is no antecedent basis in the claims for the phrases "an adhesive mixture of claim 1" and "the adhesive mixture of

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claim 1" recited in claims 9-12 and 15. There is no antecedent basis in the claims for the phrase "the pulmonary system" at claim 51, line 2, and at claim 153, line 2. It is suggested that "the" be changed to "a" in this phrase. Claims 130-132 are identical in scope with claims 95-97. It is believed that this is because the dependencies of claims 130-132 are incorrect. Claim 157 appears to recite the same limitation found in claim 119.

9. Claim 16 is objected to because of the following informalities: At claim 16, line 2, "a" should be changed to "an". Appropriate correction is required.

10. Claims 16, 40, 74, 106, and 141 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 16 requires -LM- to be an oligomeric diradical, but is dependent upon claim 15, which requires -LM- to be a diester radical. Claims 40, 74, 106, and 141 recite a crosslinking agent concentration range with a lower limit of 5 mg/ml. This range is broader than the crosslinking agent concentration range with a lower limit of 50 mg/ml recited in claims 36, 70, 102, and 137, upon which claims 40, 74, 106, and 141 depend.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

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12. Claims 119, 120, 133-136, and 157 are rejected under 35 U.S.C. 102(b) as being anticipated by Doi et al (U.S. Patent No. 4,839,345). Doi et al teach an adhesive composition comprising egg albumin and a crosslinking agent comprising polyoxyethylene and a N-hydroxysuccinimide activated leaving group having the structure recited in Preparation Example 6. The compositions adhere to skin. See also Tables 1-5, Examples 6 and 9. Cure times are 10 minutes. See Example 1.

13. Claims 128-132 are rejected under 35 U.S.C. 103(a) as being obvious over Doi et al (U.S. Patent No. 4,839,345). Application of Doi et al is the same as in the above rejection of claims 119, 120, 133-136, and 157. Doi et al do not teach a peel strength or burst pressure for their albumin-based adhesive composition. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to optimize the peel strength and burst pressure for the albumin-based adhesive compositions of Doi et al by optimizing reactant ratios because it is desirable in the art to maximize peel strength and burst pressure and because it is routine in the art to optimize reactant ratios so as to optimize the adhesive properties of the final product.

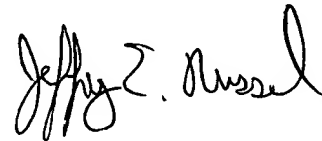
14. Fortier is cited as art of interest, but is not deemed to teach or suggest the claimed invention. Although the reference discloses crosslinking serum albumin with activated polyethylene glycol, there is no indication in the reference that the composition possesses adhesive or sealant properties. The composition's disclosed use as a contact lens or other ophthalmic device (see, e.g., column 8, lines 55-56) implies that the composition is not adhesive. Further, the

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reference's disclosed albumin concentrations (see, e.g., column 6, lines 30-31, and column 15, lines 6-8) are significantly lower than those recited in instant claim 1.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (703) 308-0254. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 305-7939 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 12, 1999